

tially free of undissolved material, whereas the article was contaminated with undissolved material. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: September 27, 1948. Default decree of condemnation and destruction.

2559. Adulteration and misbranding of dextrose solution and adulteration of sodium chloride solution. U. S. v. 330 Flasks, etc. (F. D. C. No. 25095. Sample Nos. 18071-K, 18073-K.)

LIBEL FILED: July 20, 1948, Southern District of Indiana.

ALLEGED SHIPMENT: During the period of March 14, 1947, to March 8, 1948, by the Continental Pharmacal Co., from Cleveland, Ohio.

PRODUCT: 330 flasks of *dextrose solution* and 36 flasks of *sodium chloride solution* at Indianapolis, Ind.

LABEL, IN PART: "Dextrose 5% in Isotonic Solution of Sodium Chloride 500 cc. * * * sterile and nonpyrogenic" and "Isotonic Solution of Sodium Chloride U. S. P. 500 cc."

NATURE OF CHARGE: Adulteration, Section 501 (b), the articles purported to be and were represented as "Dextrose and Sodium Chloride Injection" and "Sterile Isotonic Sodium Chloride Solution for Parenteral Use," respectively, drugs the names of which are recognized in the United States Pharmacopoeia, an official compendium, and their quality and purity fell below the official standards since the articles were contaminated with undissolved material; and the *dextrose solution* was contaminated with living micro-organisms and pyrogen.

Misbranding, Section 502 (a), the statement "This product is sterile and non-pyrogenic" on the label of the *dextrose solution* was false and misleading.

DISPOSITION: September 24, 1948. Default decree of forfeiture and destruction.

2560. Adulteration and misbranding of dextrose in isotonic solution of sodium chloride. U. S. v. 14 Flasks * * *. (F. D. C. No. 25357. Sample Nos. 6696-K, 6708-K.)

LIBEL FILED: August 11, 1948, Western District of New York.

ALLEGED SHIPMENT: On or about June 3, 1947, by the Continental Pharmacal Co., from Cleveland, Ohio.

PRODUCT: 14 flasks of *dextrose in isotonic solution of sodium chloride* at Gowanda, N. Y. The solution was contained in hermetically sealed flasks and was intended for intravenous injection. That intravenous use was contemplated was evidenced by the statement on the flask label "For the purpose of filling and rinsing the tubing this unit contains 50 cc in excess of the declared volume * * * Single dose container."

LABEL, IN PART: "Dextrose 5% In Isotonic Solution of Sodium Chloride 1000 cc * * * sterile and non-pyrogenic."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Dextrose Injection in Isotonic Sodium Chloride Solution," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and the quality and purity of the article fell below the official standard since it was contaminated with living micro-organisms and contained pyrogen.

Misbranding, Section 502 (a), the label statement "This product is sterile and non-pyrogenic" was false and misleading as applied to an article contaminated with living micro-organisms and pyrogen.

DISPOSITION: September 13, 1948. Default decree of condemnation. The product was ordered delivered to the Food and Drug Administration, for testing purposes.

2561. Adulteration of sodium iodide and sodium salicylate. U. S. v. 67 Ampuls * * *. (F. D. C. No. 23967. Sample Nos. 79517-H, 14603-K.)

LIBEL FILED: On November 24, 1947, Northern District of Illinois.

ALLEGED SHIPMENT: On or about July 18, 1947, by Bristol Laboratories, Inc., from Syracuse, N. Y.

PRODUCT: 67 ampuls of *sodium iodide and sodium salicylate* at Chicago, Ill.

LABEL, IN PART: "20 cc. size ampuls Sodium Iodide and Sodium Salicylate Sterile Solution for Intravenous Use."

NATURE OF CHARGE: Adulteration, Section 501 (b), the product purported to be and was represented as a drug, "Sodium Salicylate and Iodide Ampuls," the name of which is recognized in the National Formulary, an official compendium, and its quality and purity fell below the standard set forth in the compendium since it was contaminated with undissolved material.

DISPOSITION: February 3, 1948. Default decree of condemnation and destruction.

2562. Adulteration of sodium salicylate and iodide with colchicine. U. S. v. 4 Cartons * * *. (F. D. C. No. 25415. Sample No. 46005-K.)

LIBEL FILED: August 26, 1948, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about June 11, 1948, from Philadelphia, Pa.

PRODUCT: 4 cartons, each containing 12 20-cc ampuls, of *sodium salicylate and iodide with colchicine* at St. Louis, Mo.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Sodium Salicylate and Iodide with Colchicine Ampuls," a drug the name of which is recognized in the National Formulary, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: January 6, 1949. Default decree of condemnation and destruction.

2563. Adulteration of vitamin B complex with distilled water. U. S. v. 92 Packages * * *. (F. D. C. No. 25631. Sample No. 25868-K.)

LIBEL FILED: September 11, 1948, District of Minnesota.

ALLEGED SHIPMENT: On or about August 4, 1948, by Hyland Laboratories, from Los Angeles, Calif.

PRODUCT: 92 packages of *vitamin B complex with distilled water* at Minneapolis, Minn.

LABEL, IN PART: "10cc. B-Complex dried * * * with sterile diluent containing * * * Distilled Water 10cc."

NATURE OF CHARGE: Adulteration, Section 501 (c), the diluent purported to be and was represented as "Water for Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and